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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,253	01/18/2002	Robert L. Stout	32265	7968

7590 05/05/2005
HOVEY, WILLIAMS, TIMMONS & COLLINS
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2405 Grand
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EXAMINER

BROWN, TIMOTHY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,253

Applicant(s)

STOUT, ROBERT L.

Examiner

Timothy M. Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 4 and 7-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 4 and 7-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Final Office Action is responsive to the communication received February 7, 2005.

Claims 3, 4 and 7-31 are pending, while claims 1, 2, 5 and 6 have been canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4 and 7-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in that the phrase "HCV antigen" in line 6 lacks antecedent basis.

Claim 12 is also indefinite because it is unclear whether "a second fluid sample" refers to (a) a second assay that is performed on the same sample as the "biological fluid sample," or (b) a separate fluid sample that has the same constituents of the "biological fluid sample."

Finally, claim 12 is indefinite because it is unclear whether "the fluid sample" in line 10 refers to "the biological fluid sample," or the "second fluid sample."

Claim 19 is indefinite in that it is unclear how the step of "contacting the fluid sample with HCV antigen" contributes to the step of "determining the optical density of said solution." In other words, there is no nexus between the contacting and determining steps.

Claim 19 is also indefinite for failing to include an essential step. Claim 19 is drawn to a method of predicting chronic HCV infection. However, the claim fails to include a resolution

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step wherein the method's comparison step lines 7 and 8 is correlated with chronic HCV infection.

Claim 30 is indefinite in the recitation of "said sample contains chronic HCV infection." It is unclear how the sample may contain chronic HCV infection because the response to HCV infection varies such that virus from the claimed sample may not cause a chronic infection in some individuals. Thus, it is unclear how the sample can contain chronic HCV.

Claim 31 is indefinite in the recitation of "said assay including *antigen* to HCV *antibodies*" This language is indefinite because referring to 'an antigen' may denote a single antigen that cross-reacts with a number of antibodies, or an antigen that binds a plurality of the same species of antibody within the same sample.

Claim 31 is also indefinite in that there is no nexus between the steps of "performing an antibody-based assay on said sample," and "determining the optical density of said sample after the antibody-based assay is performed." As recited, it is unclear how the performing step contributes to the resolution of the sample's optical density.

Finally, claim 31 is indefinite for failing to include an essential step. Claim 31 is drawn to a method of predicting chronic HCV infection. However, the claim fails to include a resolution step wherein the measurement of optical density is correlated with chronic HCV infection.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3, 4 and 7-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheffel et al. ("Scheffle").

Applicants' invention is drawn to a method of detecting chronic hepatitis C virus (HCV) comprising:

- obtaining a sample from an individual;
- performing an HCV immunoassay on said sample;
- determining the optical density of said sample;
- comparing the optical density of the sample with a set of optical density values that are obtained from samples taken from (a) individuals known to have chronic HCV, and (b) individuals who have cleared the HCV infection but remain positive for HCV antibody;
- and determining the individual has chronic a HCV infection based on the comparison of the sample with the set of optical density values.

Scheffel teaches many features of the claimed invention including performing an immunoassay on a sample from an individual suspected of having chronic HCV infection (page 8, lines 13-17), determining an optical density of the sample after performing the immunoassay (page 13, lines 6-15), and determining that the individual has chronic HCV based on a comparison of the level of antibody in the sample (as determined by optical density), with a predetermined level of antibody.

Although Scheffel does not expressly disclose detecting chronic HCV infection based on optical densities, including such a step would have been an obvious change. This is because Scheffel teaches using optical density as a measure of antibody concentration and it is well within the knowledge generally available to the skilled artisan to substitute one variable (i.e.

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optical density) for another (i.e. antibody concentration) when the variables are directly correlated. Thus, one skilled in this art would have been motivated to modify Scheffel to compare optical density values - instead of antibody concentration levels - in order to reduce the number of method steps. Moreover, one skilled in the art would have had a reasonable expectation of success using such a strategy since Scheffel teaches that optical density may be used to derive antibody concentration which is the variable that defines chronic HCV infection. Therefore, it would have been obvious to one of ordinary skill to modify Scheffel to detect chronic HCV infection based on a comparison of optical densities.

Scheffel does not expressly disclose detecting chronic HCV based on a comparison of optical density with a correlation curve. However, Scheffel expressly suggests this step because Scheffel teaches that chronic HCV can be predicted based on “a single point determination” if an antibody concentration (i.e. optical density) value is compared with values from a number of known chronic and self-limiting case (p. 12, lines 13-17). One skilled in the art could reasonably expect such a method to succeed since Scheffel teaches that elevated antibody levels, relative to a standard, can provide a prediction of chronic HCV infection.

Claims 13-18 and 20-25 recite a number of probability ranges, such as “said certain probability that the individual has chronic HCV infection being less than about 10% . . .” (e.g. claim 15). This limitation reads on Scheffel’s providing a prediction that, based on antibody titer, the individual does not have chronic HCV. This is because by providing a prediction that the individual does not have chronic HCV, Scheffel provides a prediction that the probability of chronic HCV infection zero (i.e. less than 10%).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

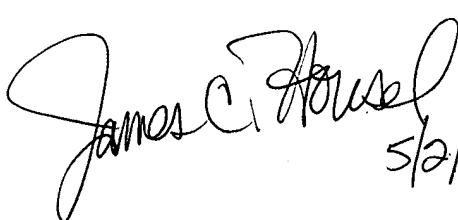
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

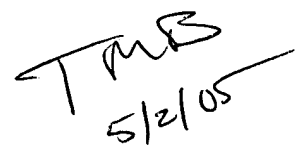
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb


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